CHAD A. READLER
Acting Assistant Attorney General
GUSTAV W. EYLER
Acting Director
Consumer Protection Branch
NATALIE N. SANDERS
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 5th Street, NW, Suite 6400-South
Washington, D.C. 20530
Telephone: (202) 598-2208
Facsimile: (202) 514-8742
E-mail: Natalie.N.Sanders@usdoj.gov

Attorneys for Plaintiff
UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

EASTERN DIVISION

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| UNITED STATES OF AMERICA,<br><br>Plaintiff,<br><br>v.<br><br>CALIFORNIA STEM CELL TREATMENT CENTER, INC., a California corporation, CELL SURGICAL NETWORK CORPORATION, a California corporation, and ELLIOT B. LANDER, M.D., MARK BERMAN, M.D., individuals,<br><br>Defendants. | No. 5:18-CV-1005<br><br>**COMPLAINT FOR PERMANENT INJUNCTION** |

Plaintiff, the United States of America, by and through undersigned counsel, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 332(a), to enjoin California Stem

Cell Treatment Center, Inc. ("CSCTC"), a California corporation, Cell Surgical Network Corporation ("CSN"), a California corporation, and Elliot B. Lander, M.D. and Mark Berman, M.D., individuals (hereafter, collectively, "Defendants"), from violating 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), and misbranded within the meaning of 21 U.S.C. §§ 352(f)(1), 352(j), and 353(b)(4), while held for sale after shipment of the drugs or one or more of their components in interstate commerce, and for violating 21 U.S.C. § 331(c) by receiving misbranded drugs in interstate commerce and delivering or proffering for delivery such drugs for pay or otherwise. An injunction is necessary to prevent Defendants from experimenting on patients with adulterated and misbranded drugs.

**Jurisdiction and Venue**

2. Jurisdiction to restrain such violations is granted to the district courts of the United States pursuant to 21 U.S.C. § 332(a). This Court also has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

**Defendants and their Operations**

4. Defendant CSCTC is a California professional corporation founded in 2010, with its principal place of business located at 72-780 Country Club Drive, Suite 301, Rancho Mirage, California 92270 ("CSCTC Rancho Mirage"), and a second establishment located at 120 South Spalding Drive, Suite 300, Beverly Hills, California 90212 ("CSCTC Beverly Hills"), within the jurisdiction of this Court.

5. CSCTC manufactures, or has caused to be manufactured, several adipose (fat) derived products ("CSCTC products"), including the following: (1) a product containing what is referred to as "stromal vascular fraction" (the "SVF product") which is manufactured from a patient's adipose tissue; (2) a product that combines SVF and Vaccinia Vaccine, Live (the "SVF/Vaccinia product"); and (3) a product containing SVF that has been expanded in culture for CSCTC by a third party (the "expanded SVF product").

6. CSCTC products are intended for autologous use, which refers to the "implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered." See 21 C.F.R. § 1271.3(a).

7. CSCTC products are used for the experimental treatment of patients who suffer from a variety of diseases or conditions, including, but not limited to, cancer, arthritis, stroke, amyotrophic lateral sclerosis ("ALS"), multiple sclerosis ("MS"), macular degeneration, Parkinson's disease, chronic obstructive pulmonary disease ("COPD"), and diabetes.

8. CSCTC products are administered to patients using a variety of methods, including intravenously; injection into specific areas of the body, including the brain and spinal cord; and via a nebulizer. CSCTC products are administered at CSCTC Rancho Mirage and CSCTC Beverly Hills, and at other locations such as a radiologist's office in Indian Wells, California.

9. Production of CSCTC products is the result of a multi-step manufacturing process. Under Defendants' current procedures, SVF production involves the recovery of adipose tissue from patients in dedicated operating rooms located at CSCTC Rancho Mirage and CSCTC Beverly Hills. The tissue recovery is accomplished by a mini-liposuction procedure, whereby a cannula is used to recover adipose tissue through an incision commonly made in the patient's posterior flank.

10. Defendants subject the recovered adipose tissue to numerous processing steps through which many components of the tissue are broken down and discarded. The process involves the addition of a collagenase solution to isolate cell components through enzymatic digestion. It also includes an incubation period, several washing steps using 5% Dextrose in Lactated Ringer's Injection, and filtration. Manufacturing employs various types of equipment, including, but not limited to, a specialized SVF-processing device identified as the "Time Machine," syringes, plungers, stoppers, adapters, and a filter.

11. Most CSCTC patients are treated with the SVF product on the day that their

adipose tissue is recovered. For intravenous administration, the SVF is added to a 100ml bag of 0.9% Sodium Chloride (NaCl) and given to the patient through an intravenous drip.

12. Labeling on the CSCTC products varies depending on whether the products are manufactured at CSCTC Beverly Hills or CSCTC Rancho Mirage. At most, however, labeling on the CSCTC products identifies only the name of the patient, date of birth, date of manufacture, and a CSCTC employee's initials. Among other things, the CSCTC products' label lacks indications for use, dosages, routes of administration, and side effects. The CSCTC products' label also does not identify the products as "Rx only."

13. Defendants manufacture the CSCTC products using one or more components shipped in interstate commerce from places outside the State of California. Components received from outside California include, for example, 0.9% Sodium Chloride Injection, USP and 5% Dextrose in Lactated Ringer's Injection, both manufactured in Illinois. Defendants' manufacturing process also involves their use of a collagenase product made in Indiana.

14. Defendants have manufactured a SVF/Vaccinia product that is a combination of SVF and Vaccinia Vaccine, Live. Vaccinia Vaccine, Live, is also known by its proprietary name ACAM2000. ACAM2000 is an FDA-approved biological product for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection. The vaccine's labeling is required to display a "black box warning" designed to call attention to serious or life-threatening product risk, including swelling of the heart tissues, brain, or spinal cord. See 21 C.F.R. § 201.57(c)(l). The SVF/Vaccinia product has been used by Defendants as an experimental treatment for patients suffering from a variety of advanced stage cancers and was administered to patients intravenously or directly into patients' tumors. The SVF/Vaccinia product contained amounts of the vaccine that greatly exceeded the vaccine's labeled dose.

15. Vaccinia Vaccine used to manufacture the SVF/Vaccinia product was shipped in interstate commerce from Georgia.

16. For their expanded SVF products, Defendants have sent recovered adipose tissue to a firm located outside of the State of California for production into SVF, which then is expanded in culture. The expanded SVF products are subsequently returned in interstate commerce to CSCTC Rancho Mirage and CSCTC Beverly Hills and administered to patients during scheduled appointments.

17. Many patients pay thousands of dollars to receive a single CSCTC product, and some patients pay much more to receive multiple treatments. Defendants have referred to this practice as "patient-funded research."

18. None of CSCTC's products have been licensed or approved by the United States Food and Drug Administration ("FDA").

19. There are not now, nor have there ever been any approved new drug applications ("NDAs") filed with FDA pursuant to 21 U.S.C. § 355(b) or (j) for the CSCTC products. There are not now, nor have there ever been any approved biologics license applications ("BLAs") filed with FDA pursuant to 42 U.S.C. § 262 for the CSCTC products.

20. Although Defendants have had discussions with FDA concerning their desire to study the SVF/Vaccinia product pursuant to an Investigational New Drug Application ("IND") under 21 U.S.C. § 355(i), no IND is currently in effect for that product, or for any of Defendants' other products.

21. Defendant CSN is a California corporation founded by Defendants Berman and Lander in 2012 that is registered to do business at 72-780 Country Club Drive, Suite 301, Rancho Mirage, California 92270, the same address as CSCTC Rancho Mirage, within the jurisdiction of this Court.

22. Through CSN, Defendants Berman and Lander control the SVF-related operations of approximately 100 for-profit affiliates, or licensees, including CSCTC. Defendant Lander has asserted that CSN affiliate doctors have administered SVF

products to over 6,000 patients.

23. Affiliates who join the CSN network are required to follow production instructions and treatment procedures developed by Defendants Berman and Lander. They are also required to purchase from CSN specialized equipment, including the Time Machine, that is identified in the protocols developed by Defendants Berman and Lander. Defendants Berman and Lander refer to CSN affiliate clinics as "sub-investigators."

24. CSN's "Guidelines for Affiliates" explicitly mandates that network affiliates must adhere strictly to CSN protocols, CSN standards, "reasonably follow price guidelines to avoid competition for patient enrollment within the network," be diligent in registering patients into the CSN Database, and use standardized forms, including specific consent forms for patient care and data collection. The guidelines also describe that affiliates have limited permission to use various trademarks and logos, including logos for California Stem Cell Treatment Center, CSCTC, and Cell Surgical Network.

25. CSN operates a one-employee warehouse at 73700 Dinah Shore Drive, Suite 301, Palm Desert, California 92211, within the jurisdiction of this Court, from which equipment and supplies are shipped to affiliates.

26. Defendant Elliot B. Lander, M.D., a board-certified urologist and surgeon, is the co-owner and Co-Medical Director of CSCTC. He is the most responsible individual at CSCTC Rancho Mirage and performs his duties at CSCTC Rancho Mirage, within the jurisdiction of this Court. He manages all firm employees at CSCTC Rancho Mirage where his activities include recovering adipose tissue from patients and manufacturing CSCTC products. Dr. Lander is the co-owner and Co-Medical Director of CSN. He is also the co-owner of Cells On Ice, Inc., which has assisted in the recovery of adipose tissue sent outside of the State of California for production into the expanded SVF product.

27. Defendant Mark Berman, M.D., a board-certified cosmetic surgeon, is the co-owner and Co-Medical Director of CSCTC. He performs his duties at the CSCTC

Beverly Hills facility, within the jurisdiction of this Court, and is the most responsible individual at CSCTC Beverly Hills where his activities include recovering adipose tissue from patients and manufacturing CSCTC products. Dr. Berman is the co-owner and Co-Medical Director of CSN and co-owner of Cells On Ice, Inc.

**The CSCTC Products Are Drugs Under the FDCA**

28. Under the FDCA, a "drug" includes any article that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B), or that is "intended to affect the structure or any function of the body," 21 U.S.C. § 321(g)(1)(C).

29. The "intended use" of a product refers, in turn, "to the objective intent of the persons legally responsible for the labeling of drugs," and is determined by such persons' expressions or may be shown, for example, by "labeling claims, advertising matter, or oral or written statements by such persons or their representatives. . . ." 21 C.F.R. § 201.128.

30. The CSCTC products are "drugs" within the meaning of the FDCA, 21 U.S.C. § 321(g)(1)(B) and (C), because Defendants' records, public statements, and information contained on Defendants' websites and elsewhere establish that CSCTC products are intended to be used in the cure, mitigation, or treatment of diseases in man and/or to affect the structure and function of the body. Examples include, but are not limited to:

a. A CSCTC brochure that markets "a solution rich with your own stem cells . . . . [u]nder investigational protocols . . . to treat a number of degenerative conditions and diseases."

b. Study protocols for Defendants' SVF/Vaccinia product that explain how the product is used to treat patients with advanced-stage cancer.

c. Study protocols developed by Defendants that detail the use of Defendants' SVF product to treat COPD and asthma, Parkinson's disease, Alzheimer's disease, MS, and ALS.

d. Records collected during FDA's recent inspections at CSCTC Beverly Hills and Rancho Mirage that document Defendants' manufacture of CSCTC products to treat patients with arthritis, MS, diabetes, stroke, macular degeneration, COPD, among numerous other diseases and conditions.

e. Product claims on Defendants' websites. See, e.g., http://stemcellrevolution.com/about-us/faqs/ (offering "cutting edge clinical trials using stem cells to carry cancer-killing biologic agents deep into cancer tissue"); www.stemcellrevolution.com/currently-studying (listing over 30 diseases or conditions that CSN is "currently studying," including MS, ALS, cardiomyopathy, lupus, and macular degeneration).

f. Numerous YouTube promotional videos, including:

1) A videotaped interview of Dr. Lander wherein he promotes SVF "for cancer therapies," arthritis, heart disease, lung disease and interstitial cystitis, and "brain conditions . . . . [by] injecting the cells directly into the brain," available at https://www.youtube.com/watch?v=otushsFxkzw.

2) A video by Dr. Berman that describes the SVF product as "magical cells in your fat" and "liquid magic" used to treat "COPD, heart disease, neurodegenerative problems, . . . interstitial cystitis . . . Peyronie's and erectile dysfunction," available at https://www.youtube.com/watch?v=SVVQrosn0gc.

3) A CSN FAQ video that describes CSN's "investigative protocols for studying . . . arthritis, neurologic disease, urologic disease" and how the same cells are "capable of fixing anything," available at https://www.youtube.com/watch?v=fWi_UzX-i_A.

31. The CSCTC products are "prescription drugs" within the meaning of 21 U.S.C. § 353(b)(1)(A) because, due to their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, they are not safe for use except under the supervision of a practitioner licensed by law to administer such drug.

32. There have been no adequate and well-controlled studies performed on the CSCTC products demonstrating that they are safe or effective for any indication.

33. The CSCTC products are "new drugs" within the meaning of 21 U.S.C. § 321(p)(1), because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. The CSCTC products are also "new drugs" within the meaning of 21 U.S.C. § 321(p)(2), because they have not been used to a material extent or for a material time under the conditions prescribed, recommended, or suggested in their labeling.

**The CSCTC Products Are Biological Products Under the PHSA**

34. Under the PHSA, a "biological product" includes any "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i).

35. The CSCTC products are "biological products" within the meaning of the PHSA, 42 U.S.C. § 262(i), because they are an "analogous product" that is "applicable to the prevention, treatment, or cure of a disease or condition of human beings." As noted above, Defendants claim that the CSCTC products treat several diseases and conditions, including, but not limited to, cancer, arthritis, stroke, ALS, MS, macular degeneration, Parkinson's disease, COPD, and diabetes.

36. A product may be both a drug and a biological product. A product that has been licensed under the PHSA is not required to also have an approved NDA under the FDCA. 42 U.S.C. § 262(j). However, the FDCA's adulteration and misbranding provisions, 21 U.S.C. §§ 351 and 352, apply to biological products. 42 U.S.C. § 262(j). As noted above, the CSCTC products have not been licensed or approved by FDA.

**The CSCTC Products Are Subject to Regulation Under the FDCA**

37. In addition to being drugs and biological products, the CSCTC products are

also "human cells, tissues, or cellular or tissue-based products" ("HCT/Ps"). HCT/Ps are defined as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d). Under limited circumstances not applicable here, some HCT/Ps can be regulated effectively solely by controlling the communicable disease risks they present through the regulations set forth in 21 C.F.R. Part 1271, even if such HCT/Ps otherwise would be regulated as drugs and biological products under the FDCA and the PHSA. The criteria found in 21 C.F.R. § 1271.10(a) distinguish those HCT/Ps regulated solely under section 361 of the PHSA (42 U.S.C. § 264) and the regulations in 21 C.F.R. Part 1271 from those HCT/Ps regulated as drugs and biological products under the FDCA and section 351 of the PHSA (42 U.S.C. § 262).

38. FDA has identified other limited circumstances, also not applicable here, under which an establishment is excepted from FDA's regulations set forth at 21 C.F.R. Part 1271. See 21 C.F.R. § 1271.15.

39. HCT/Ps that do not fall within one of the exceptions in 21 C.F.R. § 1271.15, and do not meet all of the criteria in 21 C.F.R. § 1271.10(a) for regulation solely under the PHSA and 21 C.F.R. Part 1271, are regulated as, among other things, drugs and biological products under the provisions of the FDCA and the PHSA, including the adulteration, misbranding, and premarket approval requirements. 21 C.F.R. § 1271.20.

40. The criteria in 21 C.F.R. § 1271.10 include the requirement that the HCT/P be "intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent." 21 C.F.R. § 1271.10(a)(2). "Homologous use" means "the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor." 21 C.F.R. § 1271.3(c).

41. The CSCTC products fail to meet 21 C.F.R. § 1271.10(a)(2)'s requirement that the HCT/P be "intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent." As described

above in paragraph 7, the CSCTC products are intended for use in the treatment of various diseases or conditions, including but not limited to, cancer, arthritis, stroke, ALS, MS, macular degeneration, Parkinson's disease, COPD, and diabetes, among others. Such uses bear no resemblance to any basic function of adipose tissue, which provides cushioning and support to, among other areas, skin and organs. Because the CSCTC products do not perform the same basic function or functions of adipose tissue, using the CSCTC products for the treatment of cancer, arthritis, stroke, ALS, MS, macular degeneration, Parkinson's disease, COPD, and diabetes is not homologous use.

42. The criteria in 21 C.F.R. § 1271.10(a) also include the requirement that the HCT/P be only "minimally manipulated." 21 C.F.R. § 1271.10(a)(1). For structural tissue, "minimal manipulation" means processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement. 21 C.F.R. § 1271.3(f)(1).

43. The CSCTC products fail to meet 21 C.F.R. § 1271.10(a)(1)'s requirement that the HCT/P be only "minimally manipulated." Adipose tissue is structural tissue. Defendants' processing of the CSCTC products, as described above in paragraph 10, alters the original relevant characteristics of the adipose tissue, including its extracellular matrix and inherent structural properties that contribute to the tissue's utility as, for example, cushioning and support for skin or organs. The production process employed by Defendants includes enzymatic digestion to break down the adipose tissue's extracellular matrix and isolate cellular components. Such processing constitutes more than minimal manipulation of the HCT/P.

44. The SVF/Vaccinia product also fails to meet 21 C.F.R. § 1271.10(a)(3)'s requirement that the manufacture of HCT/P's "not involve the combination . . . with another article," with certain exceptions inapplicable here. Because the SVF/Vaccinia product involves the combination of SVF derived from adipose tissue and Vaccinia Vaccine, Live, the HCT/P is "combined with" another article and the criterion at 21 C.F.R. § 1271.10(a)(3) has not been met.

45. As noted above, FDA has also identified certain circumstances under which an establishment is not required to comply with 21 C.F.R. Part 1271. See 21 C.F.R. § 1271.15. One exception from 21 C.F.R. Part 1271 applies to "an establishment that removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure" ("same surgical procedure exception"). 21 C.F.R. § 1271.15(b). Defendants do not qualify for the same surgical procedure exception because, among other things, the adipose tissue recovered from individuals is subjected to processing rendering the CSCTC products no longer "such HCT/Ps," but a collection of cellular components isolated from adipose tissue. Thus, Defendants do not qualify for the same surgical procedure exception in 21 C.F.R. § 1271.15(b), or any other exception from 21 C.F.R. Part 1271.

46. Because the CSCTC products do not meet all of the criteria in 21 C.F.R. § 1271.10(a), and do not fall within any of the exceptions in 21 C.F.R. § 1271.15, the CSCTC products are regulated as drugs and biological products under the FDCA and section 351 of the PHSA and are subject to the provisions of the FDCA and the PHSA, including the FDCA's adulteration, misbranding, and premarket approval requirements. 21 C.F.R. § 1271.20.

**The CSCTC Products Are Adulterated**

47. Regardless of whether a drug is actually deficient in any respect, a drug is deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice ("CGMP") to assure that such drug meets the requirements of the FDCA as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess. 21 U.S.C. § 351(a)(2)(B).

48. FDA investigators inspected CSCTC Rancho Mirage from June 17-26, 2017, and CSCTC Beverly Hills from June 21-27, 2017. Those inspections showed that the methods used in, and the facilities and controls used for, the manufacture, processing,

packing, and holding of CSCTC products do not conform to and are not operated or administered in conformity with CGMP. *See* 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210-211; *see also* 21 C.F.R. Parts 600-680 (setting forth additional standards and manufacturing requirements applicable to biological products). At the close of the inspections, FDA investigators issued lists of inspectional observations ("Form FDA 483s") to Defendants Berman and Lander. The CGMP violations observed during the inspections included, but were not limited to, the following:

a. Failure to establish and follow appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile, including validation of all aseptic and sterilization processes, as required by 21 C.F.R. § 211.113(b).

b. Failure to establish written procedures for production and process control designed to assure the drug products have the identity, strength, quality and purity they purport or are represented to possess, as required by 21 C.F.R. § 211.100(a).

c. Failure to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity, as required by 21 C.F.R. § 211.160(b).

d. Failure to conduct appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms, as required by 21 C.F.R. § 211.165(b).

e. Failure to establish a system for monitoring environmental conditions to prevent contamination during aseptic processing, as required by 21 C.F.R. § 211.42(c)(10)(iv).

49. Because Defendants do not manufacture the CSCTC products in a manner that conforms to CGMP, the CSCTC products are adulterated within the meaning of the FDCA, 21 U.S.C. § 351(a)(2)(B).

**Adverse Events**

50. During FDA's inspections at CSCTC Rancho Mirage and CSCTC Beverly Hills, investigators reviewed numerous records that documented adverse events that occurred after treatment with CSCTC products, including but not limited to the following:

a. On February 6, 2017, a patient with COPD lost consciousness and was hospitalized after being treated with Defendant's SVF product intravenously and with a nebulizer at CSCTC Beverly Hills. The event was not identified as an adverse event by Defendants, yet a notation in the patient's records indicated that in the future, the patient should only receive intravenous SVF and "NO nebulizer."

b. On April 16, 2016, a patient who received SVF injected through a catheter into the brain at CSCTC Beverly Hills was hospitalized when testing revealed evidence of infection.

c. On March 21, 2016, a patient who received SVF in her knee at CSCTC Beverly Hills experienced an infection and was unable to walk for six months.

51. Defendants' records also revealed that patients treated at CSN affiliates – using the same protocols and equipment as Defendants – experienced adverse events that occurred after treatment with SVF products. These adverse events include, but are not limited to, a patient who received SVF injected through a catheter into the brain was hospitalized for headache and confusion, and a patient who reported two retinal detachments after receiving SVF injections in her eyes.

**The CSCTC Products Are Misbranded**

52. The CSCTC products are misbranded within the meaning of the FDCA, 21 U.S.C. § 352(f)(1), because they are drugs and their labeling fails to bear adequate directions for use, and because they are not exempt from the requirements of 21 U.S.C. § 352(f)(1).

53. The CSCTC products are misbranded within the meaning of the FDCA, 21 U.S.C. § 353(b)(4) because they are prescription drugs and, at times prior to dispensing,

their labels fail to bear, at a minimum, the symbol "Rx only."

54. Defendants' SVF/Vaccinia product is misbranded within the meaning of the FDCA, 21 U.S.C. § 352(j), because it is "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

**Defendants Violate the FDCA**

55. Defendants violate 21 U.S.C. § 331(k) by causing the adulteration of CSCTC products within the meaning of 21 U.S.C. § 351(a)(2)(B), while they are held for sale after shipment of one or more of their components in interstate commerce, as alleged in ¶¶ 13, 15, 47-49.

56. Defendants violate 21 U.S.C. § 331(k) by causing the misbranding of CSCTC products within the meaning of 21 U.S.C. §§ 352(f)(1), 352(j), and 353(b)(4), while they are held for sale after shipment of one or more of their components in interstate commerce, as alleged in ¶¶ 12, 13, 15, 52-54.

57. Defendants CSCTC, Berman, and Lander violate 21 U.S.C. § 331(c) by receiving drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(f)(1) and 353(b)(4) in interstate commerce and delivering or proffering for delivery such drugs for pay or otherwise, as alleged in ¶¶ 16, 17, 52-54.

**Continuing Noncompliance**

58. Defendants are well aware that the CSCTC products are subject to regulation as drugs and biological products under the FDCA and PHSA, and that their conduct violates the law and could lead to regulatory action.

59. On December 30, 2015, FDA issued a Warning Letter to one of Defendants' affiliates that manufactured SVF using Defendants' protocols and procedures. The Warning letter explained that the SVF products produced by the affiliate failed to meet the criteria in 21 C.F.R. § 1271.10(a), including that the HCT/P be "intended for homologous use" and only "minimally manipulated." FDA advised the CSN affiliate that the SVF product's intended uses caused it to be a drug under 21

U.S.C. § 321(g) and a biological product under 42 U.S.C. § 262(i), and that it was not lawfully marketed under the FDCA or PHSA. The Warning Letter cautioned that failure to promptly cease the violative conduct could result in regulatory action, including an injunction of the affiliate's operations. During subsequent discussions with FDA representatives, Defendants indicated their familiarity with the situation and the Warning Letter, but continued their production of CSCTC products.

60. In February 2017, during an interview with a professor at the University of California Davis School of Medicine, Defendants Berman and Lander confirmed that CSN affiliates were growing adipose stem cells in a lab and had not obtained any FDA approvals for their clinical approach. When asked why CSN had not obtained FDA approval, Berman and Lander indicated that CSN intended to treat patients with their products in order to collect data before contacting FDA. See https://ipscell.com/2017/02/cell-surgical-network-large-group-of-us-clinics-using-lab-expanded-stem-cells-in-patients/.

61. In July 2017, FDA investigators completed inspections at CSCTC Rancho Mirage and CSCTC Beverly Hills and discussed their inspectional observations with Defendants Berman and Lander. During the inspections, Defendants maintained that CSCTC products were not drugs or biological products and their activities were not governed by the FDCA. Defendants Berman and Lander sent FDA written responses to the inspectional observations noted by FDA investigators during the July 2017 inspections. The responses argued that Defendants' practices are not subject to FDA oversight and offered no indication that they intended to cease producing CSCTC products and administering them to patients.

62. On August 31, 2017, during a telephone call between Defendant Berman and FDA's Director of Biological Products Operations, Office of Regulatory Affairs, Defendant Berman reiterated his belief that there is a fundamental problem with FDA regulations and how they are applied. He also reiterated his position that SVF is not a drug and a surgical standard should be applied to his activities.

63. On August 25, 2017, United States Marshals seized five vials of ACAM2000 intended to be used by Defendants and another company in the production of Defendants' SVF/Vaccinia product used to treat cancer patients. An FDA press release issued after the seizure noted that the SVF/Vaccinia product was an "unapproved stem cell product." In response, Defendant CSN issued a press release stating that FDA's statements showed "a lack of understanding surrounding autologous surgical procedures." Defendants' press release noted that Defendants had submitted "multiple IDE and IND applications to the FDA" but omitted the fact that no such submissions had been cleared or approved. The press release also conceded that Defendants already were "conducting a pilot study" involving cancer patients. See https://stemcellrevolution.com/wp-content/uploads/CSN-FDA-press-release-8.28.17.pdf.

64. On October 17, 2017, in a response to a request from Defendants for an in-person meeting with the FDA Commissioner, FDA's Director of the Office of Biological Products Operations, Office of Regulatory Affairs, reiterated to Defendants that their activities violated FDA regulations and that the CSCTC products were not being lawfully marketed. Upon receiving FDA's response, Defendant Berman sent FDA several messages that stated, among other things, his belief that SVF is not a drug and that CSCTC is performing surgical procedures.

65. Defendants' conduct demonstrates their persistent refusal to comply with the law. Unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. § 331(k) by causing the adulteration and misbranding of drugs in the manner alleged herein, and 21 U.S.C. § 331(c) by receiving misbranded drugs in interstate commerce and delivering or proffering for delivery such drugs for pay or otherwise.

WHEREFORE PLAINTIFF PRAYS:

I. That Defendants, CSCTC, CSN, Elliot B. Lander, and Mark Berman, and each of their officers, agents, representatives, employees, attorneys, and all persons in active concert or participation with any of them, be permanently restrained and enjoined from (1) directly or indirectly doing any act with respect to a drug (including a biological

product) that results in the drug being adulterated or misbranded within the meaning of the FDCA, if such act is done while such drug, or one of its components, is held for sale (whether or not the first sale) after shipment in interstate commerce, in violation of 21 U.S.C. § 331(k), and (2) receiving in interstate commerce any drug (including a biological product) that is misbranded, and delivering or proffering for delivery such drug for pay or otherwise, in violation of 21 U.S.C. § 331(c).

II. That FDA be authorized pursuant to the injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug and/or drug component to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

III. That the Court award Plaintiff costs and other such relief as the Court deems just and proper, including equitable monetary relief.

Dated: May 9, 2018

Respectfully submitted,

CHAD A. READLER
United States Department of Justice
Acting Assistant Attorney General
Civil Division

GUSTAV W. EYLER
Acting Director
Consumer Protection Branch

/s/ Natalie N. Sanders
NATALIE N. SANDERS
Trial Attorney
Consumer Protection Branch

Of Counsel:

ROBERT P. CHARROW
General Counsel

REBECCA K. WOOD
Chief Counsel
Food and Drug Division

PERHAM GORJI
Deputy Chief Counsel for Litigation

MICHAEL SHANE
Associate Chief Counsel for Enforcement
United States Department of Health and Human Services
Office of the General Counsel
White Oak 31, Room 4554
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Telephone: (301) 796-8593